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The use of Sprint in scientific thinking

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Abbreviations
PPCR: Principles and Practice of Clinical Research
RQ: research question

INTRODUCTION

Clinical research is the scientific discipline that conducts investigations to test scientific hypotheses and theories in the healthcare field (Fregni, 2018).

Randomized clinical trials are the best evidence in the hierarchy of research designs, but a great number of these studies fail to achieve completion (Mendelsohn, 2010, p 316). This leads to economic losses and exposes patients to unnecessary risks in studies that may eventually be discontinued.

In the article "Why have clinical trials in sepsis failed?", the author discussed that most of the trials did not result in any new treatments (Marshall, 2014). He believes that many complex factors can lead to failure in sepsis research, including assumptions, expectations, economic and regulatory aspects. However, the most relevant factor is a poorly designed research model. Thus, he thinks that sepsis researchers must reconsider the study design to achieve successful trials.

Every study starts with a challenge that needs to be formally established as a research question (RQ). Defining the proper RQ is critical for the success of the overall investigation (Fregni, 2018). Failure to define the right question will lead to an inevitable loss of time and resources.

But what if we could find an approach that simplifies this process and helps us procure the right, or at least the most accurate RQ, using fewer resources and guided by a method that is completed in a short time?
Sprint "is a five-day process for answering critical business questions through design, prototyping, and testing ideas" created by Google Ventures (**Figure 1**). It was conceived to help organizations decide which products should be developed, which processes should be improved, or which markets should be targeted (Knapp, 2016).

This year, "Principles and Practice of Clinical Research" (PPCR) course adapted the Sprint process for the development of their Group Project, which is one of the most important activities, that aims to produce a clinical trial protocol.

As of the publication of this communication, we have not found published articles relating the Sprint

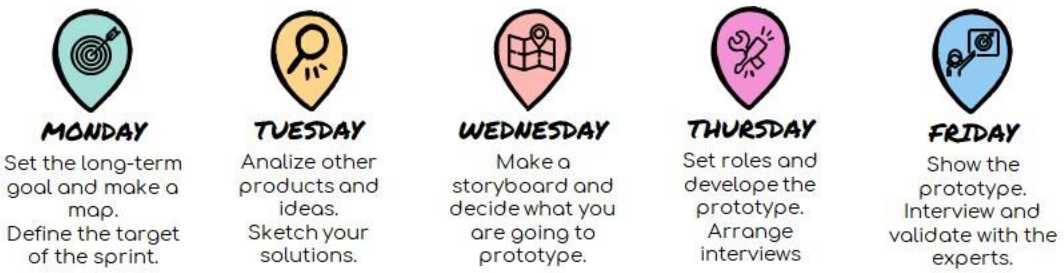

Figure 1. Sprint process

process to scientific thinking, making it a novel tool in this area. However, it has been used in different industries including tech companies, coffee shops, education, government, and insurance companies, amongst others (Sprint Stories, 2020).

We aim to describe this process and its specific application in the definition of the RQ for the clinical trial protocol development.

MATERIAL AND METHODS

We searched the Pubmed database, Google Scholar for the terms: "Sprint", "Sprint process", "Sprint methodology", "scientific thinking", and their combinations.

We have found very few published articles on Sprint and no articles were found combining "Sprint" with "scientific thinking".

RESULTS

According to the Sprint process and our adaptation for clinical trial protocols, on Monday, the method starts defining the long-term goal, which, in this case, is the clinical trial protocol. The team should establish the pathophysiology of the disease under study, search for related bibliography to find gaps in knowledge, define the intervention mechanisms, search for previous trials, and talk to experts. By the end of the day, the team will have a list of questions, which will eventually become the RQ.

Tuesday is dedicated to the elaboration of the list of ideas, trying to transform them into different RQ. The team must consider and define five primary elements: Population, Intervention, Control group, Outcome, and Time (PICOT) (Fregni, 2018).

On Wednesday, participants assess each RQ identifying pros and cons. To be considered valid, each RQ must prove to be Feasible, Interesting, Novel, Ethical, and Relevant (FINER criteria) (Fregni, 2018). By the end of the day, the team should vote and decide which RQ is going to be developed.

Thursday is devoted to refining the selected RQ based on the work conducted in the previous days. The PICOT components are described in detail and the output is validated following the FINER criteria.

The last day (Friday) is reserved for validating the final RQ with experts. Interviews are conducted to determine whether it is worth investing the time and resources needed for the investigation.

One recent example of Sprint applied to the scientific method is an internet publication from Cancer Immunologic Data Commons and the National Cancer Institute (Biswas, 2020).

They applied Sprint to a cancer immunology research study. The five-day goal was to develop an immune-related biomarker database to improve clinical trials in cancer immunotherapies. At the end of the five days, they found this methodology really enriching, achieving the goal in less time and more productively.

DISCUSSION

A new paradigm in research endeavors is emerging. Although Sprint was created for different fields (other than research), we believe it can be applied to clinical research study design. According to the present adaptation, the Sprint process in clinical research should be implemented differently: some activities might need more than one day to be accomplished.

Strengths of Sprint

- Structured yet flexible process that yields quick and robust results.
- Each member of the team knows their role and the agenda from the beginning.
- Everyone knows the process and the next steps all the time.
- Potentially leads to successful study designs, avoiding failure in clinical trials.

Limitations of Sprint

- The process takes less time than what is required for scientific research.
- Cannot be applied to all phases of the research process.
- There is a lack of experience in the use of this method in the scientific field.

Other methods for defining the RQ

Lean Inception (Caroli, 2018) might present a similar approach to Sprint. This is another five-day process that aims to get the definition of the product that the team will build. In contrast to Sprint, Lean Inception will not produce a prototype but a starting point that sets the foundation to begin the product's development. In either case, the outcome is the selected RQ. As with Sprint, we did not find clinical applications of this method. It would be interesting to analyze its effectiveness in the research process.

Use of Sprint in new scenarios

In times when the COVID pandemic is causing a worldwide impact and fast and validated information is needed, Sprint would stand as an answer, proving its usefulness and strength. Many initiatives are willing to find a cure for this illness, and we believe that this approach could help investigators focus on the right RQ to sustain their endeavors, finding sooner a treatment that would slow down the spread of the virus and save lives.

Likewise, as it is a new tool for this area, we should conduct studies and evaluate its true effectiveness. If it succeeds, further questions may arise, including:

- Could it be applied for other phases of the clinical trial protocol development process?
- Would it be invalid due to regulatory barriers in randomized clinical trials?
- Considering that it seeks quick answers, could it be harmful or unethical for volunteers, participants, and patients?

In the context of the PPCR program, it would be interesting to compare both methodologies during Group Project development. We could consider conducting a prospective study next year evaluating Sprint vs. the conventional method.

CONCLUSION

The RQ is the most important step in any clinical research study since it drives the whole process and determines the consequent success or failure.

Sprint is a novel tool to create better clinical research designs and RQ in a faster and more effective way.

While it has proven its benefits in many industries, it has not been widely used in this field yet, so we believe that further analysis should be performed in order to assess its utility in scientific thinking.

Conflict of interest and financial disclosure

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